

REMARKS/ARGUMENTS

Claims 12 – 25 are pending in the application. Claims 8 – 11 are canceled by this Amendment. Claims 1 – 7 were canceled by a previous Amendment. New claims 14 – 25 are added by this Amendment. No new matter is added.

Applicants thank the Examiner for her discussion of proposed amendments and of the relevant cited art in a telephone interview on January 5, 2011. The amendments and remarks below are directed to the specific points raised by the Examiner during the interview as well as in the Office Action.

Claims 8 – 13 are rejected under 35 U.S.C. §112, 2nd paragraph, as indefinite.

Claim 8, which was directed to the inhibitor itself, is canceled by this Amendment, mooted both §112 rejections thereto. Claims 9 – 11 (which had limited the citral-containing product, rather than the inhibitor) are also canceled by this Amendment, and are added as new claims 21 – 23 that properly depend from product claim 13, with minor changes in wording for consistent antecedent basis and grammar.

Claims 12 and 13 are rejected as indefinite as to the “dipping method” for extracting the tea leaves. Applicants submit that the term “dipping” would have been readily understood by a person of ordinary skill in the art because the term is not a special or indistinct term but a usual term, particularly as to tea. According to the Cambridge Advanced Learner’s Dictionary, the meaning of the term “dip” is “[t]o put something into a liquid for a short time.” However, to expedite prosecution, the term “dipping method” has been deleted from independent claims 12 and 13, thereby overcoming the §112 rejections thereto.

Accordingly, for the reasons above, Applicants respectfully request reconsideration and withdrawal of the §112, 2nd paragraph rejections to claims 12 and 13.

Claims 8 – 11 are rejected under 35 U.S.C. §102(b) over J.K. Lin et al., “Survey of Catechins, Gallic Acid, and Methylxanthines in Green, Oolong, Pu-erh, and Black Teas,” *J. Agric. Food Chem.*, 1998, vol. 46, pp. 3635-3642 (hereinafter, “Lin et al.”).

Lin et al. is a newly-cited reference that is cited in the Office Action for teaching extracts of semi-fermented and fermented tea leaves obtained by adding 10 grams of tea leaves to 100 mL of boiling water and steeping for 10 minutes (p. 3636).

Independent claim 8, which had been directed to an inhibitor made of an extract from tea leaves, is canceled by this Amendment, along with its dependent claims 9 – 11, mooted the §102(b) rejections to claims 8 – 11 over Lin et al.

Claims 8 through 13 are rejected under 35 U.S.C. §103(a) over: (1) WO 98/58656 to Bank et al. (hereinafter, “Bank et al.”) in view of U.S. Patent No. 4,839,187 to Mai et al. (hereinafter, “Mai et al.”), and (2) Bank et al., in view of U.S. Patent No. 4,673,530 to Hara (hereinafter, “Hara”).

The §103(a) rejections are maintained from the previous Office Action.

As noted above, Applicants have canceled claims 8 – 11, mooted the §103(a) rejections to those claims. The §103(a) rejections to independent claims 12 and 13 are discussed below.

Claim 12 is now amended to be directed to a “method for **inhibiting formation of p-cresol or p-methylacetophenone** causing the generation of deterioration smell of a citral or citral-containing product” [emphasis added]. The method includes the steps of **adding an inhibitor of p-cresol or p-methylacetophenone to the citral or citral-containing product** in an amount between about 1 – 500 ppm, where the inhibitor comprises an extract obtained by extracting one part per weight of semi-fermented or fermented tea leaves 2 – 100 parts per weight of a solvent selected from water, ethanol or a mixture thereof **by heating under reflux at 100°C or less**, and **inhibiting formation of p-cresol or p-methylacetophenone by the**

added inhibitor [emphasis added]. Claim 12 recites that the above steps inhibit generation of a deterioration smell caused by p-cresol or p-methylacetophenone in the citral or citral-containing product.

New claims 24 and 25, which depend from claim 12, further limit the amount of the added inhibitor to 1 – 100 ppm and 5 – 30 ppm, respectively. These narrower ranges reflect the preferred ranges and the test examples in the application. For example, although the inhibitor can be added at 1 – 500 parts per million (ppm) (page 8, line 2; page 13, line 18), a particularly preferred range is 1 – 100 ppm (page 13, lines 7 and 19), which exerts the desired inhibition of deterioration smell without influencing the original flavor of foods, oral care products, etc. (page 13, lines 2 – 6). Specifically for extracts of **fermented** tea leaves, Extraction examples 23, 24 and 25 (page 71, line 9, to page 72, line 26) disclose extractions conducted by heating under reflux for one hour to produce an extract (inhibitor) that was tested at a measurement concentration of 20 ppm (page 71, line 18; and page 72, lines 6 and 22), and was added in the following amounts to these products: yogurt drink (10 ppm), lemon drink (5 ppm), lactic acid drink (10 ppm), orange drink (20 ppm), and oral cleaning rinse (10 ppm) (see page 71, line 8, to page 77, line 11). Similarly, extracts of **semi-fermented** tea leaves were added in the following amounts to these products: yogurt drink (10 ppm), lemon drink (5 ppm), lactic acid drink (10 ppm) orange drink (20 ppm), and oral cleaning rinse (10 ppm) (see page 82, line 7, to page 85, line 16).

Claim 13, as amended, now recites a **product** having: a **major base component**, a **citral component in the major base component**, and an **inhibitor of p-cresol or p-methylacetophenone** in the product. The inhibitor is present in an amount between 1 – 500 ppm, and comprises an extract obtained by extracting one part by weight of semi-fermented tea leaves or fermented tea leaves 2 – 100 parts by weight of a solvent (water, ethanol, or an ethanol/water mixture) by heating under reflux at 100°C or less. The **product produces less p-cresol or p-methylacetophenone derived from the citral component**, thereby **generating less deterioration smell** [emphasis added].

New claim 14, which depends from claim 13, further limits the “major base component” in the product to a liquid selected from the group consisting of: purified water, distilled water, ethanol, milk, and any combinations of these. Support for these particular major base products are disclosed on page 76, line 17, to page 77, line 10 (also page 85, lines 3 – 16), where, for instance, the product (oral cleaning rinse) has a major base component that is purified water in an amount of 72.1 grams; as well as the combination of distilled water and ethanol in the apple and grape flavors (page 78, lines 9 – 17; page 79, lines 1 – 7; page 86, lines 15 – 23; and page 87, lines 2 – 13). New claim 15, which also depends from claim 13, further limits the “major base component” to a solid or semi-solid selected from the group consisting of: fat, oil, gelatin, yogurt, and combinations of these. As an example in support, the application provides specific examples of a major base component that is a combination of shortening (i.e., fat) and corn oil (page 77, line 12; page 85, line 18) to which an extract of semi-fermented or fermented tea leaves is added to inhibit production of p-cresol or p-methylacetophenone.

New claims 16 and 17 narrow the amount of the inhibitor in the product to between 1 – 100 ppm and 5 – 30 ppm, respectively. Support in the application for these specific amounts is found in the remarks for claim 12 above.

Claims 18 – 23 further define the product in narrower product categories; for example, to an oral care composition, which is disclosed generally (page 13, lines 19 – 20, and page 15, lines 8 – 10), and specifically as an oral care rinse having an inhibitor extracted from fermented or semi-fermented tea leaves at Example 26 (page 76, line 16, to page 77, line 10) and Example 31 (page 85, lines 2 – 16), respectively. Support for other product categories recited in claims 19 – 23 are found generally on page 14, line 14, to page 16, line 1, and specifically with an inhibitor extracted from fermented or semi-fermented tea leaves in Test Examples 27 – 30 (pages 73 – 76) and Test Examples 32 – 35 (pages 82 – 85). As noted above, new claims 21 – 23 are similar to original claims 9 – 11 (which were canceled), because these claims further define the product and so more properly depend from product claim 13.

As discussed during the interview above, Test Example 36 (page 92, line 17, to page 93, line 23), shows that adding 15 ppm of black tea extract or oolong tea extract significantly inhibited the generation of p-cresol and p-methylacetophenone (see Table 6 on page 93, lines 17 – 18), in marked contrast to the potent anti-oxidants L-ascorbic acid (page 93, line 21), which had little or no inhibitory effect on generation of p-cresol and p-methylacetophenone. Similar test results were found in Test Example 37 (page 94, line 1, to page 95, line 9); as shown in Table 37, addition of 15 ppm of either a black tea leaves extract or oolong tea leaves extract to a lemon-flavored drink inhibited generation of p-cresol and p-methylacetophenone (as demonstrated by sensory evaluations on a scale of 0 to 4), in contrast to addition of 60 ppm of the strong anti-oxidant L-ascorbic acid. As shown by the data in these Test Examples, “the generation of p-cresol-like or p-methylacetophenone-like deterioration smell could be strongly inhibited by adding an inhibitor ...comprising an extract of ...black tea leaves, oolong tea leaves...On the other hand, [an] inhibiting effect for the generation of p-cresol-like or p-methylacetophenone-like deterioration smell could hardly be observed even by adding rutin, chlorogenic acid, or L-ascorbic acid.” (page 95, line 9, to page 96, line 7).

Similar results were found in tests of the rinse in Test Example 38 (page 96, line 7, to page 98, line 11). As shown most clearly in Table 38 (page 97, line 21, to page 98, line 3), addition of 30 ppm of a black tea leaves extract or an oolong tea leaves extract to a model base product strongly inhibited generation of p-cresol-like or p-methylacetophenone-like off-odors, as measured on a scale of 0 to 4 (1.6 and 1.3, respectively). This result is markedly different from those found with strong anti-oxidant L-ascorbic acid at 200 ppm, which had little or no effect in preventing generation of p-cresol-like or p-methylacetophenone-like off-odors (3.8 on a scale of 4).

During the interview on January 5, 2011, the Examiner inquired whether the temperature of 40°C that is stated next to L-ascorbic acid in Table 38 (page 98) would also apply to the extracts of black tea leaves and oolong tea leaves. To address this inquiry, Applicants confirm that the rinses with additions of black tea leaves extract and oolong tea leaves extract **were also stored at 40°C** in the same manner as the product with L-ascorbic

acid added, and note that the description of temperatures for the two tea extracts dropped out of Table 38 at the time of filing the application. However, in paragraph [0473] on page 96, the following description confirms the storage temperature and storage period:

“To 100 g of the above model base were added 0.5 g of lemon fragrance and 0.3 g of a 1% by weight solution of each inhibitor for the generation of deterioration smell in a 50% by weight aqueous solution of ethanol to prepare a model base for weakly acidic rinse. The base was stored in a thermostat at 40°C for 14 days. There were similarly prepared model bases for weakly acidic rinse by adding L-ascorbic acid, rutin, or chlorogenic acid as a comparative antioxidant in concentrations as shown in Table 3[38]. Each base was stored in a thermostat at 40° C for 14 days to prepare a model base for weakly acidic rinse. Sensory test was carried out by selecting a panel consisting of skilled 10 experts. As a control, the scented model base product stored under refrigeration free of inhibitors for the generation of deterioration smell and antioxidants (evaluation score: 0) and the scented model base product stored at 40°C for 14 days free of inhibitors for the generation of deterioration smell and antioxidants (evaluation score: 4) were used, and the scented model base product added with inhibitors for the generation of deterioration smell and antioxidants was relatively evaluated for degree of flavor deterioration. The results are as given in Table 38. In Table 3[38], score for evaluation is an average of each panel as marked according to the following score standard.” (pages 96 – 97).

The results in the Test Examples above also correlate with the experimental data provided in the “Kiyohara Declaration” that was filed with the previous Amendment. The Kiyohara Declaration compared anti-oxidant activity of a black tea extract (prepared by Extraction Example 24 in the present application) with rosmarinic acid, which is the anti-oxidant disclosed in Bank et al. Briefly, the anti-oxidant activities of the black tea extract and rosmarinic acid, respectively, were tested by the 1,1-diphenyl-2-picrylhydrazyl (DPPH) radical scavenger activity test, and the results charted relative to the activity of L-ascorbic acid, which was a control assigned a value of 100.0 for comparative purposes.

As shown by the graphs of Concentration versus Absorbance in Figures 1 and 2 of the Kiyohara Declaration, rosmarinic acid exhibited much higher anti-oxidant activity as compared with L-ascorbic acid (136.9 versus 100.0), whereas the black tea extract exhibited much lower anti-oxidant activity as compared with L-ascorbic acid (66.9 versus 100.0). Based on the analysis of this experimental test data and review of Bank et al., the Kiyohara Declaration

concludes that “it would not have been obvious for one of ordinary skill in the art to have substituted an extract from tea for the rosemary extract of Bank et al.”

When the Kiyohara data is combined with the data in the Test Examples above, one of skill in this technology would not reasonably have assumed that extracts from fermented or semi-fermented tea leaves could be substituted for rosmarinic acid simply because each extract can act as an anti-oxidant. In fact, the Test Examples clearly show that, while extracts of black tea leaves and oolong tea leaves strongly inhibit deterioration smells that are p-cresol-like or p-methylacetophenone-like, far stronger anti-oxidants such as L-ascorbic acid actually had little or no inhibitory effect on generation of these two compounds derived from citral that cause off-odors.

In addition, as noted in the previous Amendment, Bank herself teaches that an anti-oxidant does not always inhibit the generation of deterioration smell of citral, as in the following passage:

“Other researchers have investigated the effects of various antioxidants on citral degradation, and specifically the formation of oxidative degradation products (compounds D, E, F, and G). Kimura et al. report that none of the free-radical terminators (antioxidants) they tested (i.e., butylated hydroxytoluene (BHT), butylated hydroxyanisole (BHA), propyl gallate, d,l- α -tocopherol, nordihydroguaiaretic acid and n-tritriacontane-16,18-dione, isolated from the leaf wax of the Eucalyptus tree) inhibited the formation of these citral oxidative degradation products in an aqueous citral solution. (Kimura, K., et al., *Journal of Agricultural and Food Chemistry*, 31:801-804 (1983); and Kimura, K., et al., *Agricultural and Biological Chemistry*, 47:1661-1663 (1983).) Because these antioxidants failed to prevent formation of oxidative products, Kimura et al. concluded that citral degradation can proceed in the absence of oxygen.” (Bank et al, page 2, lines 12 – 21).

For all of the above reasons, Applicants respectfully submit that it would not have been obvious to one of ordinary skill in the art “to have substituted an extract from tea known to be an effective antioxidant, as taught by Hara, for the rosemary extract of Bank et al. in order to provide a citral containing product protected from flavor deterioration,” as suggested in the Office Action.

In addition, Mai et al. clearly discloses that his method requires treating tea leaves at temperatures **greater than 120°C** (col. 2, lines 16 – 19) to obtain the anti-oxidant agents such as gallic acid (see also Mai et al.'s disclosures of aqueous extractions conducted at temperatures **from 120°C to 210°C**, at col. 1, lines 44 – 46; and Example 1 that has a first extraction at **110 – 120°C**, followed by a second extraction at **190 °C**). By contrast, independent claims 12 and 13 each require that the inhibitor “compris[es] an extract obtained by extracting one part by weight of semi-fermented tea leaves or fermented tea leaves 2 – 100 parts by weight of a solvent selected from water, ethanol or a mixture thereof by heating under reflux at 100 °C or less” [emphasis added]. Consequently, independent claims 12 and 13 (and their dependent claims 14 – 25) now expressly distinguish over Mai et al.

Moreover, as discussed in the previous response, Mai et al. provides the following descriptions of the anti-oxidant activity of extracts of tea leaves:

“It is also reported in the literature that certain tea extracts have antioxidant properties, e.g., extracts of tea leaves, tea grounds, tea sweepings and tea wastes, but in all the tea extracts so far described, the antioxidant activity is generally very low and the application of each extract is limited to a restricted class of food materials.” [emphasis added] (Mai et al. at col. 1, lines 33 – 39)

“We have found surprisingly, that in the aqueous extractions of black tea leaves at temperatures from 120°C to 210°C, certain extracts are formed which contain appreciable quantities of gallic acid. These extracts have an antioxidant activity comparable with or superior to synthetic antioxidant systems...” [emphasis added] (Mai et al. at col. 1, lines 44 – 47).

Based on these descriptions by Mai et al., one would have expected the antioxidant activity of the tea leaves in the present claims would have been expected to be very low, unless the extraction was conducted at the higher temperatures (120°C to 210°C) taught in Mai et al. to form gallic acid. This is yet another reason that it would not have been reasonable for a person of ordinary skill in this art to have combined Bank et al. with Mai et al. to arrive at the method and product of claims 12 and 13.

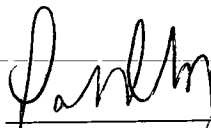
Hara discloses extracts of unfermented or semi-fermented tea leaves as anti-oxidants, where the extractions are in hot water or ethanol. Of note, Hara expressly excludes fermented tea (col. 1, line 58). However, Hara fails to disclose or suggest a “method for inhibiting formation of p-cresol or p-methylacetophenone causing the generation of deterioration smell of a citral or citral-containing product” including a step of “adding an inhibitor of p-cresol or p-methylacetophenone to said citral or citral-containing product,” [emphasis added], as now recited in claim 12. Hara also fails to disclose a product containing “a citral component” and “an inhibitor of p-cresol or p-methylacetophenone in said citral containing product,” let alone where the product “produces less p-cresol or p-methylacetophenone derived from said citral component,” as in claim 13.

Accordingly, for the reasons above, Applicants respectfully submit that independent claims 12 and 13, as well as their dependent claims 14 – 25, are in condition for allowance over the cited art, and respectfully request issuance of a Notice of Allowability for these claims.

Again, Applicants thank the Examiner for her guidance and interpretation of the cited art during the interview. In the event that there are remaining issues that would clarify any of the amendments or arguments above, the Examiner is invited to contact the undersigned attorneys at any time.

Respectfully submitted,

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